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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,156	02/25/2004	Lakshman R. Sehgal	3840-006-27	8149

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Supervisor, Patent Prosecution Services  
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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT PAPER NUMBER

1633

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/785,156

Applicant(s)

SEHGAL ET AL.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 3-5, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal an adenoviral vector comprising coding sequence for human thrombomodulin, classified in class 424, subclass 93.2.
- II. Claim 10, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal an adeno-associated virus vector comprising coding sequence for human thrombomodulin, classified in class 424, subclass 93.2.
- III. Claim 11, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal a retroviral vector comprising coding sequence for human thrombomodulin, classified in class 424, subclass 93.2.
- IV. Claims 12 and 13, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal a lentiviral vector comprising coding sequence for human thrombomodulin, classified in class 424, subclass 93.2.
- V. Claim 14, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal a herpes viral vector comprising coding sequence for human thrombomodulin, classified in class 424, subclass 93.2.
- VI. Claim 18, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal a liposomal vector comprising coding sequence for human thrombomodulin, classified in class 514, subclass 44.

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- VII. Claim 19, drawn to a method for treating thrombotic disease in a mammal by administering to the mammal naked DNA vector comprising coding sequence for human thrombomodulin, classified in class 514, subclass 44.
- VIII. Claims 24-29, drawn to a method for treating thrombotic disease in a mammal by administering recombinant cells that produce human thrombomodulin, to the mammal, classified in class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons. Each of the inventions involves a nucleotide sequence encoding human thrombomodulin or a variant of it, and using a delivery means to administer the nucleotide sequence to a mammal for treatment of thrombotic disease. The groups differ with respect to the delivery means used in each. Each uses a different viral vector, non-viral vector or cell carrying the nucleotide sequence. Each of these delivery means and their use in gene therapy involves different technical considerations and thus different examination considerations, and would require a separate non-overlapping search. Consequently, it would be a burden to search and examine more than one of the claimed inventions.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for each group is not required for any other group, restriction for examination purposes as indicated is proper.

Claims 1, 2, 6-9, and 15 link(s) inventions I, II, III, IV, and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 6-9, and 15. Claims 16, 17, and 20-23 link(s) inventions VI and VII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 16, 17, and 20-23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

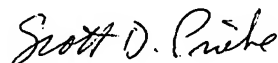
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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.  
Primary Examiner  
Art Unit 1633